

NOTICE OF INTENT

Pursuant to the provisions of La. R.S. 40:996.1 *et seq.*, the Secretary of the Louisiana Department of Health (“LDH”) hereby gives notice of intention to adopt a rule declaring the following:

I. 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)- 1,3-dihydro-2H-benzimidazol-2-one

(commonly called “brorphine” and hereinafter sometimes referred to as “the substance”) as a dangerous substance and issuing a dangerous substance stop order prohibiting the sale, distribution, manufacture, or dispensing of the substance. The Secretary considered the factors set forth in La. R.S. 40:996.3(A) in determining that the substance constitutes a dangerous substance. In accordance with La. R.S. 40:996.5(C), the following information is hereby provided:

(1) An explanation of the basis and rationale for the intended action, a summary of the information, and data supporting the intended action:

The Secretary intends to adopt said rule because of her determination that the substance poses a threat to the health of the citizens of the State of Louisiana.

The substance is a potent synthetic opioid that has been identified as the cause of death in numerous fatalities since mid-2019. Between June and July 2020, seven drug related deaths involving brorphine occurred in the U.S. (Krotulski, A. J.; Papsun, D. M.; Noble, C.; Kacinko, S. L.; Nelson, L.; Logan, B. K. Public Health Alert: The Rise of Brorphine - A Potent New Synthetic Opioid Identified in the Midwestern United States. July 2020). The first fatality known to be caused at least in part by brorphine in Louisiana occurred in Jefferson Parish in October, 2020. It has been encountered as a single substance and in combination with substances such as heroin and fentanyl. The pharmacological effects include analgesia, euphoria, and respiratory depression. The substance is available for purchase from multiple internet sites and is referred to as “intended for research and forensic application.” Brorphine has not been approved for medical and/or industrial use and there are no published studies on safety for human use. Brorphine has a similar potency to fentanyl, making it one hundred times more potent than morphine. The substance has a very high potential for abuse, has no accepted medical or industrial use in the United States, and there is no safety data for its use in humans.

(2) The time, the location, and the manner in which interested persons may present their views thereon:

Interested persons have until 4:30 p.m. on December 5, 2020, to submit a request for oral argument or presentation concerning the proposed rule, and until 4:30 p.m. on December 12, 2020, to submit data, views, comments, or arguments in writing concerning the proposed rule. Such requests or comments should be addressed to Brian R. Warren, Food and Drug Unit, Sanitarian Services Section, Office of Public Health, Mail Bin # 10, P.O. Box 4489, Baton Rouge, LA 70821-4489, or faxed to (225) 342-7672. If requests or comments are to be shipped or hand-delivered, please address the information as shown above and deliver to the Bienville Building, 628 N. 4th Street - Room 166, Baton Rouge, LA 70802. If a timely request for an opportunity for oral presentation or argument is made as provided herein, then a public hearing will be held on December 19, 2020. Please call (225) 342-1342 to find out if a public hearing is being held.

(3) *A statement that the intended action complies with the provisions of R.S. 40:996.1 through 996.7:*

The intended action and rule complies with the provisions of R.S. 40:996.1 through 996.7.

(4) *The text of the proposed rule:*

Rule

Pursuant to the authority granted by La. R.S. 40:996.1 et seq., the Secretary of the Louisiana Department of Health and Hospitals has determined that the following substance constitutes an imminent hazard to the public health, safety, and welfare, and, accordingly, is hereby declared to be a “dangerous substance”:

- I. 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)- 1,3-dihydro-2H-benzimidazol-2-one**

A “dangerous substance stop order”, as defined in La. R.S. 40:996.2, prohibiting the sale, distribution, manufacture, or dispensing of the above-listed dangerous substance, is hereby issued and declared.

The Secretary’s finding that the above-listed substance is a “dangerous substance”, and the issuance herein of a “dangerous substance stop order” concerning said substance, is based upon the Secretary’s consideration of the factors set forth in La. R.S: 40:996.3(A) and the following findings and determinations as set forth in La. R.S: 40:996.3(B):

1. ***The substance has a high potential for abuse.*** Because the substance has no legitimate medicinal use and is a highly potent drug to which severe physical ailments have been attributed, any use thereof constitutes abuse.
2. ***The substance has no current medical use in treatment in the United States.*** After consulting with the State Health Officer, the Secretary has determined that the substance has no accepted medical use in the United States or any other country.
3. ***There is a lack of accepted safety for use of the substance under medical supervision.*** The substance has no accepted medical use. Moreover, neither the Secretary nor the State Health Officer is aware of any scientific studies concerning the potency of the substance. Use of the substance even under medical supervision would therefore be unsafe and unacceptable.
4. ***There is an imminent hazard to the health, safety, and welfare of the citizens of Louisiana requiring the substance to be declared a dangerous substance and the issuance of a dangerous substance stop order as authorized by the provisions of this Section.***

The above-listed rule shall, unless a legislative oversight hearing is conducted and the rule is found unacceptable by the legislative oversight committee and the governor does not disapprove of the action taken by the legislative oversight committee, become effective on December 30, 2020, and remain in effect through the sixtieth day after final adjournment of the 2021 regular session of the Louisiana Legislature.